(1 of 2)

VERTEX® Reconstruction System
510(k) Summary

NOV 14 2008

November 2008

I. **Company:**

Medtronic Sofamor Danek USA
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738

Contact: **Melisa Lansky, M.B.A.**
Sr. Regulatory Affairs Specialist

II. **Proposed Proprietary Trade Name: VERTEX® Reconstruction System**

III. **Classification Name(s):** Spinal Interlaminal Fixation Orthosis; Class: II; Product Code(s): KWP and Regulation No.: 888.3050

IV. **Description:** The VERTEX Reconstruction System is a posterior system, which consists of a variety of shapes and sizes of plates, rods, hooks, screws, multi-axial screws, and connecting components, which can be rigidly locked to the rod in a variety of configurations, with each construct being tailor-made for the individual case. Titanium ATLAS® cable may be used with this system at the surgeon's discretion. See the package inserts of both of those systems for labeling limitations.

The VERTEX Reconstruction System is fabricated from medical grade titanium, medical grade titanium alloy, and medical grade cobalt chromium. Medical grade titanium, medical grade titanium alloy, and/or medical grade cobalt chromium may be used together. Never use titanium, titanium alloy, and or/cobalt chromium with stainless steel in the same construct. The VERTEX Reconstruction System includes a retaining ring for the multi-axial screw made of Shape Memory Alloy (Nitinol – NiTi). Shape Memory Alloy is compatible with titanium, titanium alloy, and cobalt chromium implants only. The posted screw connectors and some multi-axial screws contain elastomeric stakes made of silicone adhesive commonly used in implantable medical devices. Do not use with stainless steel.

To achieve best results, do not use any of the VERTEX Reconstruction System implant components with components from any other system or manufacturer unless specifically labeled to do so in this or another MEDTRONIC document. As with all orthopedic and neurosurgical implants, none of the VERTEX Reconstruction System components should ever be reused under any circumstances.

V. **Indications for Use**:
When intended as an adjunct to fusion in skeletally mature patients using allograft and/or autograft of the occipitocervical spine, cervical spine, and the thoracic spine, (Occiput-T3), the VERTEX Reconstruction System is indicated for the following:

DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history

K083071 (2 of 2)

and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors.

Occipitocervical Components: Plate Rod/Plates/Rods/Occipital Screws/Hooks
The occipitocervical plate rods, plates, rods, occipital screws, and hooks are intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the occipitocervical junction and the cervical spine. When used to treat these occipitocervical and cervical conditions, these screws are limited to occipital fixation only. The screws are not intended to be placed in the cervical spine.

Occipitocervical constructs require bilateral fixation to C2 and below.
Note: Segmental fixation is recommended for these constructs.

Hooks and Rods
The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

Multi-axial Screws/Connectors
The use of multi-axial screws is limited to placement in T1-T3. The screws are not intended to be placed in the cervical spine.
Titanium ATLAS® Cable System to be used with the VERTEX Reconstruction System allows for cable attachment to the posterior cervical or thoracic spine.

In order to achieve additional levels of fixation, the VERTEX® Reconstruction System may be connected to the CD HORIZON® Spinal System rods with the VERTEX® rod connectors. Refer to the CD HORIZON® Spinal System package insert for a list of the CD HORIZON® Spinal System indications of use.

VI. **Substantial Equivalence**: Documentation was provided demonstrating that the VERTEX® Reconstruction System is substantially equivalent to other commercially available posterior fixation systems and other pre-enactment devices including the VERTEX® Reconstruction System in K042402 (SE 10/1/04), K042789 (SE 12/21/04), and K081297 (SE 6/11/08). The results of mechanical testing performed for the subject VERTEX® Reconstruction System components were equivalent to the testing performed for the predicate VERTEX® Reconstruction System components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2008

Medtronic Sofamor Danek
% Ms. Melisa Lansky, M.B.A.
Sr. Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K083071
Trade/Device Name: VERTEX® Reconstruction System
Regulation Number: 21 CFR 888.3050
Regulation Names: Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: KWP
Dated: October 14, 2008
Received: October 15, 2008

Dear Ms. Lansky:

This letter corrects our substantially equivalent letter of November 14, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K083071

Device Name: VERTEX® Reconstruction System

Indications for Use:

When intended as an adjunct to fusion of the occipitocervical spine, cervical spine, and the thoracic spine, (Occiput-T3), the VERTEX® Reconstruction System is indicated for skeletally mature patients using allograft and/or autograft for the following:
DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors.

Occipitocervical Components: Plate Rod/Plates/Rods/Occipital Screws/Hooks
The occipitocervical plate rods, plates, rods, occipital screws, and hooks are intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the occipitocervical junction and the cervical spine. When used to treat these occipitocervical and cervical conditions, these screws are limited to occipital fixation only. The screws are not intended to be placed in the cervical spine.

Occipitocervical constructs require bilateral fixation to C2 and below. Note: Segmental fixation is recommended for these constructs.

Hooks and Rods
The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

Multi-axial Screws/Connectors
The use of multi-axial screws are limited to placement in T1-T3. The screws are not intended to be placed in the cervical spine.
Titanium ATLAS® Cable System to be used with the VERTEX® Reconstruction System allows for cable attachment to the posterior cervical or thoracic spine.

In order to achieve additional levels of fixation, the VERTEX® Reconstruction System may be connected to the CD HORIZON® Spinal System rods with the VERTEX® rod connectors. Refer to the CD HORIZON® Spinal System package insert for a list of the CD HORIZON® Spinal System indications of use.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083071